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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/675,705	09/30/2003	Mark S. Ortiz	END5102.0515147	6304

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FROST BROWN TODD LLC
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EXAMINER

RYCKMAN, MELISSA K

ART UNIT	PAPER NUMBER
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3773

MAIL DATE	DELIVERY MODE
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10/30/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/675,705

Applicant(s)

ORTIZ, MARK S.

Examiner

Melissa Ryckman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on received on 7/25/07.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4,8-12 and 33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,4,8-12,33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This office action is in response to claims filed 7/25/07.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 8, 9, 10 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yencho et al. (US 7004949) in view of Huebsch et al. (US 5853422). Yencho teaches an anastomosis device capable of forming an anastomosis between two gastrointestinal tissue lumens of a gastrointestinal tract and capable of passage of gastrointestinal contents there through, comprising:

- A proximal ring (112)
- A distal ring (113)

- A plurality of proximal arms (124) each attached to the proximal ring at one end and having a distally directed other end (fig. 12)
- A plurality of distal arms (123) attached to the distal ring at one and having a proximally directed other end (fig. 12)
- A center ring (111) coupling the proximal end of each distal arm to the distal end of each proximal arm;
- Wherein the anastomosis device forms a cylindrical shape with a central longitudinal axis extending therethrough with the proximal and distal arms longitudinally aligned therewith when the anastomosis device is in an unactuated position (Fig. 15, 121, col. 10, ll. 32-36, the device is simply considered rotated) and the anastomosis device has a rivet shape (portion 143) wherein the proximal and distal arms each extend radially outward (Fig. 15) relative to the longitudinal axis when actuated by a longitudinal compressive force (rotation and compressive force) to reach an actuated position.
- And when the anastomosis device is in either the unactuated (fig. 12) and the actuated (fig. 20) position, a substantially unobstructed passageway (fig. 16) is provided through the anastomosis device (110), the passageway extending from a proximal end of the proximal ring to a distal end of the distal ring and wherein when the passageway passes through a ring, the passageway has substantially the same diameter as the ring (fig. 16), the proximal arms are radially staggered relative to the distal arms to form a tortuous path of apposed tissue (Fig. 14 and 15).

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- Wherein the device is formed from a formable material wherein when the device is moved from a first shape to a second shape, the material permanently deforms into the second shape (fig. 20)
- Wherein the proximal and distal arms include a hinge (121)

Yencho fails to teach a latching mechanism operably configured to lock at a reduced longitudinal spacing two selected from a group consisting of the proximal ring, the distal ring, and the center ring comprising at least one interiorly disposed hook extending within the passageway and comprising an interference fit formed between the rings. Huebsch teaches a device comprising proximal, center and distal rings connected by proximal and distal arms, wherein in the unactuated position comprises a cylindrical shape, and in the actuated position comprises a rivet shape, and is intended for securement to tissue, wherein the device comprises a latching mechanism (242) and the center ring comprises at least one interiorly disposed hook (240) extending within the passageway and comprising an interference fit formed between the rings in order to securely and mechanically lock the device in its actuated configuration.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Yencho with a locking mechanism as taught by Huebsch in order to securely and mechanically lock the device in its actuated configuration.

Claim 4, is rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Yencho and Huebsch in view of Corcoran (US 6379368). The

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combination of Yencho and Huebsch teaches all limitations of preceding dependent claim 1, but fails to teach wherein the proximal arms are radially staggered with the distal arms. Corcoran teaches a device for placement on opposing sides of tissue, wherein the proximal extending tissue contacting portions are staggered with respect to the distal extending tissue contacting portions as seen in fig. 1 in order to allow the device to be used in a variety of physical anomalies of a variety of sizes and shapes. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the combination of Yencho and Huebsch with staggered tissue contacting portions on the proximal and distal sides in order to allow the device to be used in a variety of physical anomalies of a variety of sizes and shapes.

Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Yencho and Huebsch in view of Barra et al. (US 5843088). The combination of Yencho and Huebsch teaches all limitations of preceding dependent claims 1 and 11 as previously described, but fails to disclose wherein a pad is outwardly disposed on each inner arm segment. Barra teaches a device wherein pads (6) are disposed on the portion touching tissue in order to gently rest the device on the tissue. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the combination of Yencho and Huebsch with pads on the portion of the device touching tissue in order to allow the device to gently rest on the tissue.

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Claim 33 is rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Yencho and Huebsch as applied to claim 1 above, and further in view of Allen et al. (US 5649938). The combination of Yencho and Huebsch teaches all limitations of preceding dependent claim 1 but fails to teach wherein the anastomosis device consists of biofragmentable material. Allen teaches the use of an anastomosis device comprising biofragmentable material in order to provide a device that stays in place until healing occurs, and is then eliminated from the body in small harmless fragments. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the combination of Yencho and Huebsch with a biofragmentable material as taught by Allen in order to provide a device that stays in place until healing occurs, and is then eliminated from the body in small harmless fragments.

Response to Arguments

Applicant's arguments filed 7/25/07 have been fully considered but they are not persuasive. The applicant generally argues the following:

- The combination of Yencho and Huebsch is incorrect
- The amendments overcome Yencho and Huebsch

The examiner respectfully disagrees with the applicant, the reasoning for the combination is stated above. Yencho and Huebsch include new limitations added to claim 1, as stated above.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melissa Ryckman whose telephone number is (571)-272-9969. The examiner can normally be reached on Monday thru Friday 7:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571)-272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MKR



MICHAEL J. HAYES
SUPERVISORY PATENT EXAMINER